

### **REMARKS**

In the Office Action dated August 25, 2006, claims 1-67 were examined with the result that all claims were rejected. The Examiner issued a non-final Office Action. In response, applicant has cancelled claims 1-14 and 26-67. In view of the above amendments and following remarks, reconsideration of this application is requested.

In the Office Action, claims 1-67 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. In addition, claims 1-67 were rejected under 35 USC §112, first paragraph, as being non-enabling for all of the methods originally claimed. The Examiner did, however, indicate that the specification was enabling with regard to osteoporosis. Accordingly, applicant has cancelled all of the original claims contained in the application as filed except for claims 15-25 directed toward a method for prophylaxis of osteoporosis. The data contained in Tables 1 and 2 in the application as filed illustrate that 2MD is unique in improving fracture strength, and the Examiner, on the previous Office Action dated June 9, 2005, has admitted that the data in Tables 1 and 2 “clearly show that 2MD is effective in increasing bone mass and bone strength of normal female rats”. Applicant refers the Examiner to paragraph [0067] on page 20 of the application as filed where the term “normal” was defined as being a subject that is not afflicted with or has not been diagnosed with a metabolic bone disease or any other disease/disorder that results in a decrease over time of bone mass.

It is well known that the disease of osteoporosis is characterized by bone fractures, and thus any compound which would increase bone mass and bone strength to thereby prevent or inhibit bone fractures from occurring so that one would not be diagnosed with osteoporosis, would be directed toward preventing or prophylaxis of osteoporosis. Thus, if one can increase bone mass of normal healthy children, adolescents, young adults and/or mature adults, one would be able to provide a skeleton that would survive the bone loss of aging in both men and women and the menopause in women. Thus, by increasing bone mass and bone strength before the onset of aging and the menopause, one would

never be diagnosed with osteoporosis even though one would have some bone loss due to aging and/or the menopause. In other words, by increasing bone mass when a person is young, one would never develop osteoporosis when one is older because one would still have sufficient bone and bone strength at the elderly age. This conclusion follows logically from what is set forth in the specification at paragraph [0067] on page 20 of the application as filed. Thus, applicant respectfully disagrees with the Examiner's conclusion that applicant has not reasonably conveyed to one skilled in the art that it had possession of the claimed invention or that the specification is not enabling. One skilled in the art would clearly understand that by "overloading" the skeleton at an early age, one would not develop osteoporosis at an older age.

Applicant thus respectfully request that Examiner withdraw the §112, first paragraph, rejections.

In the Office Action, claims 1-67 were rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 17-29 of U.S. Patent 5,843,928. The Examiner states that although the claims of the '928 patent are drawn to a method of treating metabolic bone disease, the instant claims different only in that they claim a method of the prophylaxis of osteoporosis rather than treating osteoporosis. The Examiner concludes that it would be obvious to one skilled in the art that 2MD would be useful in the prevention of osteoporosis as well as in the treatment of osteoporosis. However, applicant respectfully disagrees for the following reasons.

First, claims 15-25 are drawn to the prevention or prophylaxis of osteoporosis, and not the treatment of osteoporosis. There is a distinct difference between prevention of a disease and the treatment of a disease, and thus the claims are not directed or intended for the same population and/or same patients. The '928 reference refers to the "treatment" of metabolic bone diseases, but never refers to the "prevention" or "prophylaxis" of osteoporosis. This is an important distinction because there are many compounds known by those skilled in the art that might treat a disease, but do not prevent the disease.

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Applicant discussed these compounds in a previous Amendment dated June 1, 2006, but it is worth repeating here.

For example, there are numerous compounds that are currently used to treat various cancers. One is Taxol which is sold by Bristol-Myers Squibb as a chemotherapy drug given as a treatment of ovarian and breast cancer. Other chemotherapy agents for treating ovarian cancer include cyclophosphamide, adriamycin, vincristin, and cisplatin. Although given as chemotherapy agents to treat cancers, none of the above five compounds should ever be given to healthy patients without cancer in an attempt to prevent a future cancer. The same is true of a steroid such as cortisone. Cortisone is a very effective anti-inflammatory medication, but no one would suggest to a person to regularly take cortisone to prevent inflammatory diseases such as bursitis or arthritis. There are obviously significant side effects to the above chemotherapy agents and steroids, and thus simply because it treats the disease does not necessarily mean that it will prevent the disease, and/or will be prescribed to prevent a disease.

The same is true of the opposite, i.e. there are drugs that prevent a disease but do not treat the disease. For example, an aspirin has long been touted as a means for preventing heart disease, but no one would ever suggest that aspirin will treat a patient that has had a heart attack. Likewise, the intake of calcium by a healthy person might help build bone mass as to prevent a diseases like osteoporosis, but no one would ever suggest that simply by taking more calcium you can treat osteoporosis. Thus, it is clear that the claimed compound 2MD is not administered to the same patient population, and also clear that it would not be obvious to one skilled in the art that simply because 2MD might treat a disease like osteoporosis that it would also prevent or would be a prophylaxis against osteoporosis.

As a result, applicant believes the Examiner should withdraw the obviousness type double patenting rejection.

In the Office Action, claims 1-43 were rejected under 35 USC §102(e) as being anticipated by DeLuca et al U.S. 5,843,928. The Examiner states that the claims being

drawn to the use of 2MD for the increase of the strength of a bone is inherently taught by the '928 prior art patent because the treatment is intended for the same population.

Again, applicant respectfully disagrees for the following reasons.

The Examiner is basically alleging that because the '928 reference teaches the treatment of various diseases with 2MD, the administration of 2MD to treat such metabolic bone diseases will also inherently teach the prevention or prophylaxis of such diseases. First, the Examiner should note that the claims have been specifically limited to only those which are directed toward the prevention or prophylaxis of osteoporosis (claims 15-25). All remaining claims have been cancelled. Thus, the following comments are directed toward preventing osteoporosis and not the broader methods which previously referred to a disease "characterized by need to increase the strength of the bone".

The Examiner's conclusion regarding inherency cannot be supported because not only does the '928 reference never discuss or state anything about the prophylaxis or prevention of osteoporosis (only the treatment of osteoporosis), but in view of the fact that other compounds as discussed above may be administered to treat disease, but not prevent the disease, the Examiner cannot state with certainty that administering 2MD to treat osteoporosis would also necessarily and inherently be recognized by those skilled in the art, without any doubt, to also prevent or be a prophylaxis against such disease. A new use of a known compound is patentable, as long as the use is not obvious. The Examiner should specifically note that the applicant is not claiming the compound per se or pharmaceutical composition per se. Applicant is claiming the use of 2MD for the prophylaxis of osteoporosis and such use is not necessarily present in the '928 reference cited by the Examiner because there is nothing the Examiner can point to in the '928 reference which would suggest to one skilled in the art that the prophylaxis of osteoporosis would be obvious. In addition, since there is clearly doubt as to whether a particular compound that treats a disease will also prevent the disease, the prophylaxis of osteoporosis cannot be inherent in the treatment of osteoporosis, as disclosed in the '928

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reference. Applicant thus respectfully requests the Examiner withdraw the §102(e) rejection.

In the Office Action, claims 1-67 were rejected under 35 USC §103(a) as unpatentable over DeLuca et al WO 02/05823. The Examiner states that the reference teaches a method of using 2MD for the treatment of metabolic bone diseases where it is desired to maintain or increase bone mass and such teaching embraces applicant's claimed invention. The Examiner states that the instant claims are broader than the prior art. However, once again, the Examiner should note that the only claims remaining are claims 15-25 which are directed specifically to the prophylaxis or prevention of osteoporosis. Thus, applicant believes the instant claims are not broader than the prior art.

Assuming the Examiner has made a prima facie case of obviousness, Applicant may rebut that prima facie case with evidence. As stated in In re Kumar et al, 76 USPQ 2d 1048 (2005), the Court of Appeals for the Federal Circuit stated:

"An applicant may rebut a prima facie case of obviousness by providing a 'showing of facts supporting the opposite conclusion.' Such a showing dissipates the prima facie holding and requires the examiner to 'consider all of the evidence anew.' Piasecki, 745 F.2d at 1472; In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976). Rebuttal evidence may show, for example, that the claimed invention achieved unexpected results relative to the prior art, In re Geisler, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997); that the prior art teaches away from the claimed invention, *id.* at 1471; that objective evidence (e.g., commercial success) supports the conclusion that the invention would not have been obvious to a skilled artisan, Piasecki, 745 F.2d at 1475; or that the prior art did not enable one skilled in the art to produce the now-claimed invention. In re Payne, 606 F.2d 303, 314-15 (CCPA 1979)."

One way referred to above in the In re Kumar et al, *supra* case that Applicant may rebut a prima facie case of obviousness is to show that the prior art did not enable one

skilled in the art to produce the claimed invention. Although published subject matter is "prior art" for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill in the art to make and use the invention. Thus, when a prima facie case of obviousness is made, rebuttal may take the form of evidence that the prior art does not enable the claimed subject matter. In the present circumstances, the prior art cited by the Examiner clearly does not enable the now claimed invention. There is nothing in the '823 reference which teaches one skilled in the art that the vitamin D compound 2MD may be useful for the prophylaxis or prevention of metabolic bone diseases characterized by a need to increase the strength of a bone. There is nothing in the '823 reference which would teach this, and the '823 reference does not provide any data to support a claim to preventing or the prophylaxis of metabolic bone diseases. The closest statement found in the '823 reference referring to non-diseased states is the fact that the reference refers to increasing both breaking strength and crushing strength of bones which evidences the use of 2MD "in conjunction with bone replacement surgery such as hip and knee replacements." The '823 reference also refers to 2MD being "an excellent candidate for an anti-osteoporosis therapy" but once again, this refers to the treatment of diseases rather than the prevention of diseases.

Finally, Applicant notes that an invention is not obvious where the prior art only provides an "invitation to explore" even though the prior art could theoretically explain the invention. This is the holding in the case of Ex parte Obukowicz, 27 USPQ 2d 1063 (B.P.A.I. 1992). In Ex parte Obukowicz, the invention concerned a method of combating plant insect pests using plant colonizing bacteria that had been genetically modified to produce a specific protein toxin. The modification was accomplished by inserting DNA encoding for the protein toxin into the chromosome of the bacteria. The genetically modified bacteria were applied to the plant or plant seed environment, which expressed the insecticidally active protein toxin consumed by plant pests.

The claimed invention was rejected as obvious in view of the reference Dean combined with various secondary references. The principal issue was whether, based on

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Dean, the suggestion or motivation was provided to render the claimed invention obvious (i.e., the incorporation of the gene into the chromosome of bacteria that produced the protein in the plant environment).

The Board held that a statement in Dean regarding combating mosquitoes using genetically engineered "natural pond microflora" was insufficient to provide the necessary suggestion or modification. As stated by the Board:

"[T]he specific statement by Dean is not a suggestion to insert the gene into the chromosome of bacteria and apply that bacteria to the plant environment in order to protect the plant. At best, the Dean statement is but an invitation to scientists to explore a new technology that seems a promising field of experimentation. The Dean statement is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it. Such a suggestion may make an approach "obvious to try" but it does not make the invention obvious."

The Board even added the following statement:

"We recognize that given the teachings in appellant's specification regarding incorporation of the gene into the chromosome and utilizing the bacteria in the plant environment, one can theoretically explain the technological rationale for the claimed invention using selected teachings from the references. This approach, however, has been criticized by our reviewing court as hindsight reconstruction."

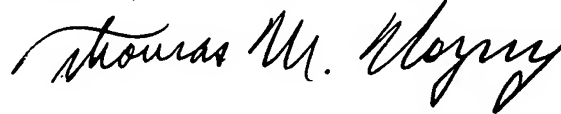
Like the holding in Obukowicz, supra, the most that can be said about what is disclosed in the '823 reference referring to increasing the strength of bone is that it presents an "obvious to try" approach to the invention, but as noted above, such an approach does not make the present claimed invention obvious. The prior art '823 reference appears to provide an invitation to explore a new technology to one skilled in the art, but that does not make the present invention obvious.

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An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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A handwritten signature in black ink, reading "Thomas M. Wozny". The signature is written in a cursive, flowing style.

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